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EXAMINER	
VAKILI, ZOHREH	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,716	ISHIKURA ET AL.	
	Examiner	Art Unit	
	ZOHREH VAKILI	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *1-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/23/2006, 03/26/2007, 02/04/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-46 are presented for examination.

Requirement for Restriction/Election

Applicant's election **with traverse** of the invention of Group III (claims 17-31 and 32-46), directed to a method of preventing or ameliorating liver diseases associated with hepatopathy wherein an omega-9 unsaturated fatty acid or a compound having an omega-9 unsaturated fatty acid as a constituent fatty acid is administered to a subject, in the replies filed 12/12/2008, is acknowledged by the Examiner.

Applicant traverses the requirement on the grounds that the groups designated by the Examiner fail to define methods and composition with properties so distinct as to warrant separate examination and search. Applicant further submits that conjoint examination and inclusion of all claims of the instant application would not present an undue burden on the Examiner and, thus, the requirement for restriction should be withdrawn.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Applicant's instant claims encompass three patentably distinct inventions for the reasons described extensively at p.2-4 of the Office Action dated 10/15/2008. The claims encompass method, compositions, and process for preparing the composition that have been shown to be patentably distinct according to the requirements of 35 U.S.C. 121 and MPEP §800, as well as the fact that each clearly circumscribes different classifications (depending upon the

inventions) and clearly different fields of search due to the divergent subject matter. Though Applicant alleges on the record that examination of all of the instantly claimed inventions would not present an undue burden upon the Examiner, Applicant fails to advance any reasons to support this position. In response thereto, the Examiner defers to the reasons presented in the Office Action dated 10/15/2008to support the asserted patentable distinction among the instantly claimed inventions and why examination of all of the claimed inventions presents an undue burden upon the Examiner. In view of the fact that (a) the inventions have acquired a separate status in the art in view of their different classification; (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter; (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries); (d) the prior art applicable to one invention would not likely be applicable to another invention; and (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph, it remains that a serious search and examination burden would be placed upon the Examiner to examine all of the instantly claimed inventions if restriction were not required.

Therefore, for the reasons above and those made of record at pages 2-4 of the Office Action dated 10/15/2008, the requirement remains proper and is hereby made **FINAL**.

Claims 1-16 are **withdrawn** pursuant to 37 C.F.R. 1.142(b) as being drawn to non-elected subject matter.

The claims corresponding to the elected subject matter are claims 17-46 and such claims are herein acted on the merits.

Claim Rejections - 35 USC § 112

Claims 32-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Since the claims do not set forth any steps involved in the method/process, they are unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Moreover, it is unclear whether Applicant is claiming: (1) a pharmaceutical product; (2) a process of making the pharmaceutical product; or (3) a method of prevention or ameliorating.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 32-46 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results

in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the prevention of negative effects of liver diseases. The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2nd 1400 (Fed. Cir. 1988) As to undue experimentation.

The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art;
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;

6) the quantity of experimentation necessary;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the art in the assessment of undue experimentation.

1) the nature of the invention; the invention is directed to a method for preventing liver diseases.

2) the breadth of the claims; the scope of the method claims include the prevention of liver diseases.

3) the predictability or unpredictability of the art; the art does not enable a person of ordinary skill in the art to make and use the claimed invention without resorting to undue experimentation. The burden of enabling one skilled in the art to prevent liver diseases would be much greater than that enabling the treatment. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing liver diseases. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active ingredients for preventing liver diseases.

No experimental evidence or mechanism of action for supporting preventing liver diseases using the specified actives would actually prevent all liver diseases by simply administering, by any method, an amount of the claim specified active agents. The specification fails to enable one of ordinary skill in the art to practice the presently claimed method for preventing the risk of liver

diseases.

The term “prevention” or “preventing” circumscribes methods of treatment having ultimate success. Since ultimate success is not as of yet reasonably possible with most diseases/disorders. The specification is viewed as lacking an adequate enablement of where liver diseases may be actually prevented.

4) the amount of direction or guidance presented; the specification and the example does not provide any guidance in terms of preventing liver diseases.

5) the presence or absence of working examples; no working examples are provided for preventing liver diseases, for example in a patient, in the specification. The applicant has not provided any competent evidence or disclosed any tests that are highly predictive for the preventative effects of the instant composition. Note that in cases involving physiological activity such as the instant case, “the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved”. See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

6) the quantity of experimentation necessary; the quantity of experimentation would be an undue burden to one of ordinary skill in the art and amount to the trial and error type of experimentation. Thus, factors such as “sufficient working examples”, “the level of skill in the art” and “predictability”, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. In view of the breadth of the claims, the chemical nature of the invention and unpredictability of preventing cardiovascular disease, and the lack of working examples regarding the activity as claimed, one skilled in the

art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

In consideration of each of factors 1-6, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17 -46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bistrian et al. (US Pat. No. 5320846) and Akimoto et al. (US Pub. No. 2004/0171127 A1.

Bistrian et al. teach a method of treating patients with clinical disorder such as liver, the dysfunction being characterized by depletion of metabolic energy sources. The treatment involves the step of administration of a total enteral nutritional diet, or as a dietary supplement. The invention includes a total enteral nutrition diet having nutritionally acceptable amounts of a lipid source, a protein source, and a carbohydrate source, (see abstract). The patient may suffer from **cancer**, a clinical liver dysfunction or trauma such as ischemia, trauma, sepsis, malnutrition, liver surgery, **hepatitis**, or liver transplant (see col. 4, lines 27-33). In that instance, the diet would consist essentially of a lipid source, a protein source, a vitamin source, a carbohydrate source, and a mineral source. Lipid sources could be from vegetable oil, fish oil or combinations that at least provide adequate amounts of essential fatty acids, e.g., linoleic or alpha linolenic acids, as well as other omega-3 or omega-9 fats (see col. 4, lines 54-62).

Akimoto et al. teach a method for preparing fat comprising a **triglyceride** having a medium chain fatty acid bonded to the 1 and 3 position and a highly unsaturated fatty acid bonded in the 2 position comprises treating a medium

chain fatty acid derivative. The lipase specifically acts on the 1 and 3-position ester bonds and the starting material fat comprises at least one omega-6 18C or more fatty acid containing at least 3 double bonds and/or **omega-9** 18C or more fatty acid containing at least 2 double bonds and no omega-3 highly unsaturated fatty acids. As a fat for use in **foods** and pharmaceuticals for treating and preventing arteriosclerosis, thrombosis and **cancer**, obtained from a Mortierella spp. The omega-9 fatty acid is 6,9-octadecadienoic acid, 8,11-ecosadienoic acid or 5,8,11-ecosatienoic acid and medium chain fatty acid derivative is a 6-12C fatty acid (preferably caprylic or caproic acid) lower alkyl ester (see abstract). The constituent fatty acid contains 45% triglyceride (see paragraph 0017).

It would have been obvious to have combined the teachings of Bistrian et al. and Akimoto et al. to produce a method of preventing or ameliorating liver diseases administering omega-9 unsaturated fatty acid.

In re Kerkhoven (205 USPQ 1069, CCPA 1980) states that "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose: the idea of combining them flows logically from their having been individually taught in the prior."

One of ordinary skill in the art would have been motivated to combine the above references and as combined teach and suggest the invention as claimed. Akimoto et al. teaches the same composition with the same mechanism to be used for the same purpose as the claimed invention. Further,

Bistrian et al. teach the same composition to be useful in treating liver diseases. Finally, one would have a reasonable expectation of success given that Barnsley and Kamijo provide a detailed blueprint for making the liquid drug preparation, and the steps of which are routine to one of ordinary skill in the art.
Thus the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and was as a whole, *prima facie* obvious.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-

direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner March 26, 2009
1614

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614